

# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 6009

ISO/TC 84

Secretariat: DS

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2015-04-20

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## Hypodermic needles for single use — Colour coding for identification

*Aiguilles hypodermiques non réutilisables — Code de couleurs pour l'identification*

ICS: 01.070;11.040.25

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This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Reference number  
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The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. In accordance with subclause 5.1 of the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard. Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 6009 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*

This fourth edition cancels and replaces the third edition, which has been technically revised.

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## Introduction

The intention of this International Standard is to specify colours to enable rapid visual identification of the outside diameter of single-use hypodermic needles. The presence of colour coding on a needle or package does not absolve the user of the responsibility to check the marked size of the needle. This standard revision defines in addition colours for more fine needles to follow the trend in the market.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to regular-walled, thin-walled, extra-thin and ultra-thin walled needles. The nominal outside diameters of needles listed in this International Standard for which colours are given are those specified in ISO 9626.

This International Standard establishes a colour code but does not specify that needles are to be colour-coded or to what portion of the needle and/or packaging the colour is to be applied. Such requirements may be given in the relevant product standards such as ISO 7864.

The Technical Committee responsible for the preparation of this International Standard has reviewed the use of instrumentally determined colour zones (chromaticity and luminance index) as used in previous editions to specify opaque colours and has decided that instrumental measurement is not practicable. The measurement of the colour zone of an opaque colour, especially of an item of the size and shape of the hub of a needle, is a complex procedure requiring apparatus and expertise that is to be found in relatively few laboratories and test houses. It may therefore be inconvenient, difficult or impossible for a manufacturer or purchaser routinely to assess compliance of a product with colour zone values. Such difficulties are compounded in the case of translucent colours, which are being used increasingly by needle manufacturers to allow air bubbles inside the hub to be seen and eliminated before injection.

As a consequence, the colours in this International Standard are only referenced by a colour reference system (RAL) or by Pantone Matching System accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance.

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 'Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters'.

## 1 Scope

This International Standard establishes a colour code for the identification of single-use hypodermic needles of nominal outside diameters in the range 34G (0,18 mm) to 10G (3,4 mm). It applies to regular-walled, thin-walled and extra-thin-walled and ultra-thin walled needles and to opaque and translucent colours.

This standard is not applicable for pen-needles.

## 2 Colour code

The colour shall indicate the nominal outside diameter of the tube of the needle, and shall be as given in Table 1.

Annex A contains certain guidance to commonly applied colour reference systems for opaque materials.

Table 1 (1 of 2) — Colour code

Designated needle size in mm	Gauge	Color (EN)
0,18	34	Orange
0,2	33	Black
0,23	32	Deep green
0,25	31	White
0,3	30	Yellow
0,33	29	Red
0,36	28	Blue-green
0,4	27	Medium grey
0,45	26	Brown
0,5	25	Orange
0,55	24	Medium purple
0,6	23	Deep blue
0,7	22	Black
0,8	21	Deep green
0,9	20	Yellow

Table 1 (2 of 2) Colour code

Designated needle size in mm	Gauge	Color (EN)
1,1	19	Cream
1,2	18	Pink
1,4	17	Red-violet
1,6	16	White
1,8	15	Blue-grey
2,1	14	Pale green
2,4	13	Purple
2,7	12	Pale blue
3	11	Green-yellow
3,4	10	Olive brown

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## Annex A (informative)

### Reference colour sample

Table A.1 (1 of 4) — Colour code

Designated needle size in mm	Gauge	Color (EN) ISO 6009:1992	RAL reference	Pantone Reference
0,18	34	Orange	2007	1575
			2003	157
			2008	164
0,2	33	Black	9004	Black 3
			9005	Black 4
			9017	Black 6
0,23	32	Deep green	6010	348
			6001	349
			6002	350
0,25	31	White	9003	11-0601
			9010	11-0602
			9016	11-0103
0,3	30	Yellow	1018	102
			1021	107
			1023	109
0,33	29	Red	3017	1797
			3018	711
			3031	187